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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Bernhard Gleich

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS

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BRIARCLIFF MANOR, NY 10510

EXAMINER

MEHTA, PARIKHA SOLANKI

ART UNIT

PAPER NUMBER

3737

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,820	Applicant(s) GLEICH, BERNHARD	
	Examiner PARIKHA S. MEHTA	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 June 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the apparatus of claim 22 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: the specification fails to meet the requirements of 37 CFR 1.74, which clearly states "[w]hen there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures, and to the different parts by use of reference letters or numerals".

Appropriate correction is required.

Claim Objections

3. Claims 2-18 and 20-22 are objected to because of the following informalities:

Art Unit: 3737

In claim 2, step a, the recitation of "magnetic field strength" is unclear in view of the recitation of multiple types of magnetic fields in the claim.

In claim 22, it is unclear whether the magnetic field set forth in step a is the same as or distinct from the varying magnetic field set forth in step e.

Applicant is advised that claim 22 recites means plus function language which does not comply with the requirements of 35 U.S.C. 112, 6th paragraph. Specifically, the claim recites, in steps a, b and e, "means to". 35 U.S.C. 112, 6th paragraph explicitly requires the recitation of "means for" in order to properly invoke the means plus function clause.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2-18 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 2-18 and 20-22 recite "an imaging magnetic field with a spatial distribution of the imaging magnetic field strength such that the examination area consists of a first sub-area with lower magnetic field strength and a second sub-area with a higher magnetic field strength". The present specification does not sufficiently enable a skilled artisan to make and use an examination area consisting of sub-areas with magnetic field strengths. Furthermore, in the event that Applicant intended to claim the sub-areas as "being subjected" to specific magnetic field strengths, the present specification does not sufficiently enable a skilled artisan to vary the imaging field strength. Applicant's attention is directed to page 3, paragraph 1 of the specification, wherein the disclosure describes the gradient field as having sub-areas subjected to different field strengths by way of superimposition of an imaging field and a varying field. Nowhere does the specification describe or illustrate the application of an imaging field with spatially variable strength.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 3737

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4, 7, 8 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 7 recites the limitation "the clumping or agglomeration" without sufficient antecedent basis.

Claim 8 recites "the varying magnetic field with a frequency in the range of 10 to 500 kHz" without sufficient antecedent basis.

Claim 20 recites that the particle "can" be reverse magnetized. It is therefore unclear whether or not the claimed method is definitively inclusive or exclusive of such limitation.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claim 22 is rejected under 35 U.S.C. 102(a) as being anticipated by Applicant's admitted prior art. Applicant admits that the system used to execute the presently claimed method, i.e. a system comprising means for executing all steps as set forth in claim 22, was known in the art prior to invention (Specification p. 4 lines 26-27).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3737

11. Claims 2-9, 11-13, 16-18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tournier et al (US PG Pubs. No. 2002/0168321), hereinafter Tournier ('321) in view of Schneider et al (US Patent No. 6,726,650), hereinafter Schneider ('650).

Regarding claims 2, 4, 5, 7 and 22, Tournier ('321) teaches an MR system and diagnostic method including means and steps for generating an imaging magnetic field over an examination area such that the area comprises one sub-area subjected to a lower magnetic field strength and a second sub-area subjected to a higher magnetic field strength, acquiring signals that depend on the magnetization in the examination area, and evaluating the signals to determine the spatial distribution of magnetic particles in the examination area (§ 10, 26, 35).

Tournier ('321) does not teach changing the spatial location of the sub-areas, nor does Tournier ('321) teach that the magnetic particles are exposed to a varying magnetic field. In the same field of endeavor, Schneider ('650) teaches subjection of magnetic contrast agents (i.e., magnetic particles) to a varying magnetic field, which is inherently applied in three dimensions and locally restricted, in order to prevent agglomeration of the particles (col. 1 line 60 – col. 2 line 9). Schneider ('650) also teaches that the magnetic field may oscillate, i.e. that the relative position of the examination area should change relative to the magnetic field, also to prevent particle agglomeration (col. 2 lines 5-6). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Tournier ('321) to include the spatial location changing and varying magnetic field application steps and means of Schneider ('650) and thereby achieve the claimed invention, in view of the teachings of Schneider ('650).

Regarding claim 3, Tournier ('321) teaches application of a gradient field (§ 2).

Regarding claim 6, Tournier ('321) teaches the particles as having an average size or expansion of at least 30 nm (§ 35).

Regarding claims 8, 9 and 12, neither Tournier ('321) nor Schneider ('650) expressly teach specific values for the varying field strength, power or frequency. However, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a magnetic field of the claimed parameter values, as it has previously been held that, where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges is obvious and unpatentable (*In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)).

Regarding claim 11, Tournier ('321) teaches that the particles comprise a magnetic core and nonmagnetic coating (§ 19 and 49).

Regarding claim 13, all magnetic fields, including the varying field taught by Schneider ('650), inherently comprise at least one pulse that decays to zero.

Art Unit: 3737

Regarding claim 16, Schneider ('650) teaches deagglomeration (i.e. application of the varying magnetic field to the particles) prior to administering the magnetic particles to the examination area (col. 1 line 60 – col. 2 line 9).

Regarding claim 17, neither Tournier ('321) nor Schneider ('650) teach application of the varying field and, thus, the deagglomeration of the magnetic particles, after the particles are administered to the examination area, or that the varying field is only applied to a part of the examination area. However, one of ordinary skill in the art would have considered it nothing more than an obvious matter of common sense to apply the varying field after administration in order to maximize the effects of deagglomeration during imaging, and to only expose the area to be imaged (i.e., a part of the examination area) to such field, as exposing more of the area would not be useful (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Regarding claim 18, the obviousness of the claimed frequency range has previously been discussed for claims 8, 9 and 12. Furthermore, a skilled artisan would have considered it nothing more than an obvious matter of common sense to alternate the imaging and varying fields of Tournier ('321) and Schneider ('650), in order to prevent the signal of the varying field from interfering the imaging field (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

12. Claims 10, 14, 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tournier ('321) and Schneider ('650) as applied to claim 2 above, and further in view of Ivkov (US PG Pubs. No. 2006/0142749), hereinafter Ivkov ('749), of record.

Tournier ('321) and Schneider ('650) do not teach the particles to be monodomain particles, nor do they teach that the varying magnetic field is chosen in view of the viscosity of the liquid medium in which the particles are dispersed. In the same problem solving area, Ivkov ('749) teaches a method of administering to a patient a solution of magnetic particles wherein monodomain magnetic contrast particles are dispersed in blood, the monodomain particles being configured to be reverse magnetized by Neel rotation, and wherein the frequency of the varying magnetic field is chosen in view of the viscosity of blood (§§ 15, 16, 22, 27, 63-64). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Tournier ('321) and Schneider ('650) to include the steps of Ivkov ('749) and thereby achieve the claimed invention, as such a modification requires nothing more than the mere combination of known prior art steps to yield predictable results, which has previously been held as obvious and unpatentable (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Art Unit: 3737

13. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tournier ('321) and Schneider ('650) as applied to claim 2 above, and further in view of Rand (US PG Pubs. No. 2005/0066961), hereinafter Rand ('961), of record.

Neither Tournier ('321) nor Schneider ('650) teach the magnetic particle to be a hard or soft multi-domain particle. In the same field of endeavor, Rand ('961) teaches an MR contrast imaging method wherein the magnetic particle is a hard or soft magnetic multi-domain particle. It would have been obvious to one of ordinary skill in the art at the time of invention to have modified the method of Tournier ('321) and Schneider ('650) to employ the particle of Rand ('961), as such a substitution would require nothing more than the mere combination of known prior art elements and steps to yield predictable results, which has previously been held as obvious and unpatentable (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 2-18 and 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10/552,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because they merely claim alternate variations and groupings of the same steps.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 3737

16. Claims 2-18 and 20-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10/552,808. Although the conflicting claims are not identical, they are not patentably distinct from each other because they merely claim alternate variations and groupings of the same steps and elements.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

17. Regarding the previous claim objections, Applicant traverses the previous objection to claims 6, 11, 12, 15, 20 and 21 for failing to further limit the claimed method on the following basis:

“The undersigned attorney is unaware of any rule that requires that each dependent method claim in a U.S. patent must set forth further steps in the method. Indeed, the undersigned attorney has prosecuted dozens of issued U.S. patents which include dependent method claims that do set forth further steps in the method. Indeed, the undersigned attorney would venture that the USPTO has issued tens of thousands of presumably-valid U.S. patents which include dependent method claims that do set forth further steps in the method.” (*Remarks p. 11*)

Examiner notes that the objection was made in view of the fact that the noted claims do **not** set forth further steps for the claimed method, i.e. that they fail to further limit the steps of the claimed invention. Accordingly, any discussion of patents wherein issued dependent claims do set forth further limiting steps for an independent method claims has no bearing on the validity of the previous objection. Furthermore, Applicant's attention is respectfully directed to 37 C.F.R. 1.75(c) which clearly states that a dependent claim must further limit the parent claim. As the limitations set forth in claims 6, 11, 12, 15 and 20 do not limit the manner in which the steps of claim 2 are executed, they do not further limit the claimed method. As Applicant's arguments are wholly unpersuasive to overcome the previous objection to claims 6, 11, 12, 15, 20 and 21 for at least the foregoing reasons, the objection is maintained and reiterated herein. Claim 7 is additionally found to be similarly deficient.

Furthermore, Applicant has failed to adequately amend the claims or submit arguments effective to overcome all deficiencies of claims 2, 4 and 7 as set forth in the previous claim objections.

Art Unit: 3737

18. Applicant's amendments are sufficient to overcome the previous rejection of claim 13 under 35 U.S.C. 112, 1st paragraph, which is hereby vacated accordingly.

19. Applicant's amendments are sufficient to overcome the previous rejections of claims 2, 3, 5, 7, 10, 16-19 and 22 under 35 U.S.C. 112, 2nd paragraph, which are hereby vacated accordingly.

20. Applicant's arguments with respect to the patentability of claims 2-18 and 20-22 in view of the prior art have been considered but are moot in view of the new ground(s) of rejection presented herein.

21. As Applicant has failed to submit a proper terminal disclaimer, the previous double patenting rejection of the claims in view of co-pending application 10/552,808 is maintained and reiterated herein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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3737

Application/Control Number: 10/552,820

Page 10

Art Unit: 3737

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Examiner, Art Unit 3737